

# Kalchem International

## Chemicals & Compounding Supplies

### CERTIFICATE OF ANALYSIS

**Product:** Erythromycin Ethylsuccinate    **Packaging:** 25kg  
**Batch No.:** C01-201510031                      **Quantity:** 200kg  
**Manu.Date:** Oct. 27, 2015                      **Expi.Date:** Oct.26, 2019

Row	TESTS	SPECIFICATIONS	RESULTS
01*	Description	White or almost white, crystalline powder, Hygroscopic.	Meets
02*	Solubility	Practically insoluble in water. Freely soluble in acetone, in ethanol and in methanol.	Meets
03	Identification	IR: Corresponds to standard	Meets
04	X-Ray Diffraction	Meet the requirement	Meets
05	Crystallinity	Meet the requirement	Meets
06	Water (K. Fischer)	N.M.T. 3.0 %	1.6%
07	Residue on ignition	N.M.T. 0.3 %	0.03%
08	Related substance	Erythromycin A enoether: N.M.T. 3.0 %	N.d.
		Erythromycin N-ethylsuccinate: N.M.T. 3.0 %	0.7%
		Any other single impurity N.M.T. 3.0 %	1.9%
*09	Residual solvents*	Tetrahydrofuran: N.M.T. 0.072% (720ppm)	N.d.
10	Assay (On the anhydrous basis)	Erythromycin B: N.M.T. 12.0 %	1.3%
		Erythromycin C: N.M.T. 5.0 %	1.7%
		Erythromycin A, B and C: N.L.T. 76.5%	91.9%
<b>CONCLUSION:</b> Conformed to the requirement of USP38 *Represents in-house specifications.			

Comments: Approved

Signature: Quality Control Department

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